

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of
SOUADA et al

Serial No. 08/354,726

Filed: 6 December 1994

For: PYRIDINE DERIVATIVES HAVING
ANTI-ULCERATIVE ACTIVITY



Atty. Ref.: 423-27

Group: 1203

Examiner: Fan

* * * * *

April 2, 1998

Honorable Commissioner of Patents
and Trademarks
Washington, DC 20231

Sir:

AMENDMENT AFTER FINAL REJECTION

This responds to the Official Action of October 7, 1997, Paper No. 17. Claims 18 and 19 are active in the application.

The final rejection raises a number of interesting issues requiring consideration and resolution.

With regard to item 2D of the Action, the unexpected advantage, namely, antibiotic activity, would have been apparent to one having ordinary skill in the art by virtue of the level of ordinary skill in the art at the time the invention was made. That *Campylobacter pylori* was involved with gastric ulcers as evidenced by the information contained in U.S. Patent No. 5,013,743 to Iwahi et al.

Under the listing of references cited see, in particular, the literature articles cited including Barry J. Marshall et al "Antibacterial Action of Bismuth in Relation to *Campylobacter pyloridis* Colonization and Gastritis" *Digestion* vol. 37, Supp. 2, (1987), as well as Buck et al, *Journal of Infectious Diseases* (April 1986). See also a discussion of the "background" portion of the specification in column 1.

While the cited patent itself has an effective date of February 12, 1990, it refers to and summarizes the level of ordinary skill in the art as of the priority date claimed in the present application, namely November 13, 1986, and in particular the Buck et al article "Relation of *Campylobacter pyloridis* to Gastritis and Peptic Ulcer", *The Journal of Infectious Diseases*, vol. 153, No. 4 (April 1986).

From these reports in the art as conveniently summarized in the Iwahi et al patent it will be apparent that investigators dealing with the treating of gastric ulcers would have been aware of the contents of these documents. At the priority date of the present invention the art shows that activity against ulcers goes hand-in-hand with activity against *Campylobacter pylori*.

Contrary to the assertions made in the Official Action, there is no legal requirement that this antibacterial property of the compounds of the present invention be described in the specification of the present application. The Court of Appeals for the Federal Circuit ("CAFC") wrote, in *In re Wright*, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989) that "the law does not require an applicant to describe in his specification every

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conceivable embodiment of the invention." *U.S. v. Telectronics Inc.*, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), citing *SRI International v. Matsushita Elec. Corp. of America*, 227 USPQ 577, 586 (Fed. Cir. 1985); and that "[a] specification may, within the meaning of 35 U.S.C. § 112, ¶1, contain a written description of a broadly claimed invention without describing all species that claim encompasses." *Utter v. Hiraga*, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988). In *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986) the CAFC stated, with respect to the enablement requirement, that "a patent need not teach and preferably omits, what is well known in the art."

Accordingly, it is submitted that there is ample information available connecting the unexpected advantage, namely effectiveness as an antibiotic as compared to other materials available to the art for the treatment of ulcers at that time.

Attached is a terminal disclaimer executed by the undersigned, who is an attorney of record, dealing with the issues raised in the last two paragraphs of page 3 of the Official Action and three of the defect noted in the first paragraph at page 4 of the Official Action.

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Responsive to items 2A and B, attached is the declaration of Mr. Sato (the original of which is in the file of a related application) presenting the same information and technical data as submitted with the Amendment and Response filed July 29, 1997.

Entry and consideration of the attached materials and above comments are solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



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